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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,160	10/25/1999	AHARON MEIR EYAL	U012190-3	1964

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EXAMINER
OH, TAYLOR V

ART UNIT	PAPER NUMBER
1625	15

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/284,160	Applicant(s) EYAL ET AL.	
	Examiner Taylor Victor Oh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continued Prosecution Application

The request filed on 4/25/2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/284,160 is acceptable and a CPA has been established. An action on the CPA follows.

The Status of Claims:

Claims 19-34 are pending.

Claims 19-34 have been rejected.

DETAILED ACTION

1. Claims 19-34 are under consideration in this Office Action.

Priority

2. Acknowledgment is made of applicants' claim for foreign priority under 35 U.S.C. 119 (a)-(d).

Drawings

3. There are no drawings filed on 4/25/2003.

Claim Rejections - 35 USC § 112

Claims 19 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a basic extractant, such as primary ,secondary and, tertiary amines having at least a total number of 18 carbon atoms, does not

reasonably provide enablement for all the possible basic extractants known in the art. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the possible basic extractants unrelated to the current invention commensurate in scope with these claims. Furthermore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without **undue experimentation.** Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation, citing *Ex Parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breath of the claims.

In the instant case, the claim encompasses various basic extractants. However, applicants' specification provide only one exemplified basic extractant (tricaprylyl amine) in all the examples. Furthermore, there is an unpredictable aspect in applying various

basic extractants to the process of recovering the lactic acid ; tricaprylyl amine extractant can not be the representative for all the possible basic extractants because they may behave differently in comparison to the tricaprylyl amine extractant; for example, under certain reaction conditions, at a specific pressure and temperature, one basic extractant has possessed a superior extractive property to another basic extractant depending on the corresponding basic chemical structures. Thus, the specification herein have failed to provide sufficient working examples to support the use of various basic extractants. Therefore, an appropriate correction is required.

The specification, while being enabling for an acid, such as sulfuric acid, does not reasonably provide enablement for all the possible acids known in the art. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the possible acids including, such as , solid aliphatic ring acids, heterocyclic acids, which are not enabled. "Foreman factors" necessarily arise because of unpredictability . In addition, long chain large molecular weight acids behave more differently than those of the claimed invention, which would require more than routine experimentation. See In re Armbruster 185 USPQ 204 (CCPA 1985) and Angstadt et al. , 190 USPQ 152 (CCPA 1990).

Claims 19 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, the phase " lactic acid in an amount greater than said portion and a lactic-acid-depleted, lactate salt-containing aqueous solution" is stated. This expression is vague as to how much lactic acid is greater in an amount than said portion and a lactic-acid-depleted, lactate salt-containing aqueous solution during the process. An appropriate correction is recommended.

In claim 31, the phase " an acid stronger than lactic acid" is stated. This expression is vague as to how much the acid is stronger than lactic acid during the process. An appropriate correction is recommended.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 19-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baniel et al (U.S. 5,510,526) .

Baniel et al discloses a process for the recovery of lactic acid, from a lactate solution composed of sodium lactate, calcium lactate or potassium lactate (see col. 11 , lines 33-34), from a fermentation broth at a pH in the range of 5.5 to 6.5 (see col. 6 , lines 6-7) by using a long-chain trialkyl amine in the presence of carbon dioxide by way of extraction (see col. 3 , lines 39-44). For example , an extractant comprising tridodecylamine and butanol is contacted with 30 % by weight aqueous lactic acid to produce 6.9 % by weight lactic acid in the organic phase (see col. 11 , Ex. 3).

In the process the organic phase obtained from the primary extraction is further subjected to a separation process such as back extraction, vaporization (see col. 4 , lines 60-65) to recover 97 % lactic acid from the original mixture (see col. 11 , lines 8-9); the solvent can be used with water for the purpose of diluting viscous trialkyl amines or enhancing the extraction (see col. 4 , lines 42-46). In addition, the depleted extractant can be replenished with butanol ,and recycled for another extraction (see col. 11, lines 13-14). Also, the reference teaches that it is plausible to recover the lactic acid by acidifying the fermentation broth with sulfuric acid; as a result, a sulfate salt is formed (see col. 1 , lines 55-59).

However, the instant invention differs from Baniel et al in that the ratio between free lactic acid and lactate salt is mentioned; at least 70 % of the free lactic acid is extracted from the aqueous solution.

Metz et al teaches a process of manufacturing compounds more than 3 mole of free lactic acid per mole of calcium lactate by using calcium oxide, calcium hydroxide, and calcium carbonate (see col. 2 ,lines 28-32).

Concerning Baniel et al's failure to mention the ratio between free lactic acid and lactate salt and the extraction of at least 70 % of the free lactic acid from the aqueous solution, Baniel et al is silent about them. However, the fermentation broth may contain some of free lactic acid and lactate salt. With respect to the 70 % of free lactic acid being extracted from the aqueous solution, the limitation of a process with respect to ranges of pH, time , ratio and concentration does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. For examples, ratio and concentration are well understood by those of ordinary skill in the art to be result-effective variables, especially when attempting to control selectivity of a chemical process.

Baniel et al does teach the process for the recovery of lactic acid, from a lactate solution composed of sodium lactate, calcium lactate or potassium lactate from a fermentation broth at a pH in the range of 5.5 to 6.5 by using a long-chain trialkyl amine in the presence of carbon dioxide by way of extraction. Furthermore, the fermentation

broth may contain some of free lactic acid and lactate salt as raw starting ingredients for the process. Therefore, it would have been obvious to the skilled artisan in the art to have motivated to optimize the ratio between free lactic acid and lactate salt of the fermentation broth in the Baniel et al through routine experimentations in order to maximize the yield of the lactic acid. This is because the skilled artisan in the art would expect the Baniel et al process to increase the production of lactic acid by the manipulation of the ratio between the free lactic acid and lactate salt in the fermentation broth as the starting ingredients.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Eyal et al (U.S. 5,766,439) discloses a process for producing an organic acid in the following steps : producing an organic acid by fermentation, adding an alkaline earth base to the fermentation, reacting the alkaline earth salt of the organic acid with a source of ammonium ions, reducing the concentrations of divalent cations, and converting the ammonium of the organic acid to free organic acid.

Sterzel et al (U.S. 5,453,365) discloses a preparation of lactates by fermentation of the mixture of sugars, conversion of the lactic acid followed by esterification during the process, in which the lactic acid is neutralized with an alkaline earth metal carbonate, added with ammonia and carbon dioxide, and the purified ammonium lactate solution is esterified with an alcohol.

Urbas (U.S. 4,444,881) discloses a process for the recovery of organic acids from dilute aqueous solutions in the following steps: adding a water-soluble tertiary

amine carbonate to the calcium salt solution to form the trialkylammonium salt of the acid, and heating the concentrated trialkylammonium salt solution to obtain the acid and the amine.

Cockrem et al (U.S. 5,210,296) discloses a process for producing a high pure lactate ester or lactic acid from a concentrated fermentation broth by acidification in the presence of an alcohol with sequential esterification, distillation of high purity ester.

Walkup et al (U.S. 5,252,473) discloses a process of producing lactic acid and esters of lactic acid in the following reactions. In the first reaction, ammonium lactate produced by a fermentation process of carbohydrate materials can be decomposed into NH_3 and lactic acid; in the second reaction, the lactic acid can be further esterified with methanol to yield methyl lactate. In the esterification of the ammonium lactate to the alkyl lactate, the reaction mixture pressure is from 1 atmosphere to 200 atmospheres and the reaction temperature is from 100^0 C. To 200^0 C.; besides, the range for the molar ratio of alcohol to ammonium salt in the reaction mixture is from 1:1 to 10:1. In the process, in order to increase the yield of methyl lactate, NH_3 can be either removed or recycled to produce ammonium lactate .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman, can be reached on (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Taylor V Oh

6/26/03